SEP 3 0 2011

K111412
510(k) Summary
May 15, 2011

1. Applicant: Steerable Technologix, LLC EIN 26-1348126 Reg # 3004588227
10301 Deerwood Park Boulevard, Suite 209
Jacksonville, FL 32256
Phone: 904-641-2599 Fax 904-641-4121
Contact: Glen Jorgensen
glenjorgensen@bellsouth.net

2. Device Name:

Proprietary Name: SurgiSteer™ electrocautery laparoscopic instruments.
Common/Usual Name: electrocautery scissors, dissector/grapser, or hook
Classification Name: 878.4400 Electrosurgical cutting and coagulation device and accessories.

3. Identification of Predicate or Legally Marketed Device

The SurgiSteer™ electrocautery laparoscopic instruments by Steerable Technologix, LLC are substantially equivalent to the "pureWrist™ electrocautery laparoscopic instruments by Cambridge Endoscopis Devices, Inc under K061425

4. *Device Desciption:*

The SurgiSteer™ line of electrocautery laparoscopic instruments are sterile, single-use disposable instruments intended for use through appropriately sized surgical trocars and consist of a proximal handle and a flexible distal end segment interconnected with a rigid 5.0 mm outer tube, all safely insulated for monoplolar electrocautery use. Distal to the distal end segment of the shaft is one of the end effectors (scissors, dissector/grasper, or hook) rotationally mounted independent of the outer tube and flexible end segment . Proximal to the end of the rigid shaft is an ergonomically shaped handle which contains: 1) a rotation knob that causes the end effector to rotate freely in both CW and CCW directions, 2) a bend wheel that causes the flexible end segment to bend >90 degrees in both left and right directions, and, 3) the actuating trigger that causes the articulating components of the end effector, if any, to open and close with sufficient force to either dissect or transect tissue. Each instrument has a monopolar energy supply cable that extends from the bottom of the handle and that can be plugged into the "the universal monopolar receptacle for footswitch-activated accessories on any commercially available generator.

5. Intended Use

The SurgiSteer electrocautery laparoscopic Instruments are sterile, single-use devices intended for use in a variety of minimally invasive surgical procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

6. Comparison of Technological Characteristics

The SurgiSteer electrocautery laparoscopic instruments have the same technological and functional characteristics as the predicate device, the "pureWrist™ electrocautery laparoscopic instruments" by Cambridge Endoscopic Devices, Inc. Each of the devices has an end effector (scissors, graspers /dissectors, or hook) that can cut or coagulate tissue using monopolar electrocautery technology. Each use sharp objects to permit the surgeon to cut or dissect tissue. Each of the devices is connected to the same or similar electrosurgical generator and use similar power ranges for operation. Each are footswitch operated and can be used in the CUT mode by depressing the CUT pedal or the COAG mode by depressing the COAG pedal. Typically, in the CUT mode a sharp edge is used is used to focus the energy for cutting. Conversely, in the COAG mode, a broad, flat face is preferable for the coagulation of bleeders. The devices have the same intended use, indications for use, and technological features including equivalent mechanical movement (bend, rotate, and actuate), equivalent electrical characteristics (monopolar) and equivalent surgical end effectors all of which yield equivalent performance. The devices have the same or similar materials of construction, packaging, and labeling. The total of these similarities supports the claim of substantial equivalence.

7. Performance Testing

Pre-clinical testing was used to evaluate performance to ensure that the device can be used as designed. The testing evaluated ergonomics of the handle, rotate knob, bend wheel, and the dissecting grasping ability and electrical insulation requirements. The studies demonstrated acceptable reliability and design performance relative to the predicate device.

8. Statement of Equivalency

Based on the design, intended use, and performance testing comparisons, the SurgiSteer line of laparoscopic instruments by Steerable Technologix, LLC are substantially equivalent to the Cambridge Endoscopic Devices, Inc. pureWrist™ laparoscopic instruments approved under K061425.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Steerable Technologix LLC
% Mr. Glen Jorgensen
10302 Deerwood Park Boulevard
Suite 209
Jacksonville, FL 32256

SEP 30 2011

Re: K111412
Trade Name: SurgiSteer™ electrocautery laparoscopic instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 15, 2011
Received: August 19, 2011

Dear Mr. Jorgensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Steerable Technologies

Indications for Use Statement

510(k) Number (if known): K111412

Device Name: SurgiSteer Electrocautery Laparoscopic Instruments

Indications for Use:

The SurgiSteer™ line of of electrocautery laparoscopic instruments are sterile, single-use devices intended for use in a variety of minimally invasive surgical procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

Prescription Use ___X___	AND/OR	Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111412